



## Commercial Grade Item Dedication

### Perspectives on Potential 10CFR Part 21 Rulemaking

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## Topical Summary

- Current Situation
- Potential impact on guidance currently being used by licensees
- Opportunities for clarification of requirements
- The importance of collaboration and coordinated communication throughout the rulemaking process

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## Current Situation

- Licensees understand and are in compliance with existing regulations
  - Clarity was established between NRC and Licensees in the late 1980s
  - NRC Staff is available and provides assistance in instances where specific questions are raised
- Established suppliers that support operations and maintenance also understand and are in compliance with existing regulations

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### Current Situation

- NRC is increasing awareness as interest in commercial nuclear power grows to accommodate plans to construct new units in the U.S.
  - Some uncertainty about dedication exists among newer participants in the industry
  - Some previously resolved points of contention are resurfacing
- Increased NRC involvement is beneficial as it has revealed opportunities for improvement

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### Current Situation

- Dedication is used more frequently to address:
  - Obsolescence
  - Schedule demand (short lead times)
- Nuclear Supply Chain
  - EPRI guidance documents written by and for licensees have recently been made available to the public ([www.epri.com](http://www.epri.com))
  - New suppliers are entering the marketplace
  - Existing suppliers are expanding application of dedication

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### Potential Impact on Existing Guidance

- Existing guidance is the basis for current licensee commercial grade item dedication programs
  - EPRI NP-5652 was conditionally endorsed by the NRC in GL 89-02
  - A series of guidance documents based upon NP-5652 and GL 89-02 provided additional direction for licensees
  - The guidance in these documents (developed over the last 20 years) is deeply embedded in licensee procedures and processes
  - NQA-1 (Edition/Addenda approved by the NRC) and other standards include similar guidance

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### Potential Impact on Existing Guidance

- Changes in regulatory requirements or terminology could result in the need to update any or all existing guidance
  - Supersede regulatory documents
  - EPRI guidance documents (~12)
  - Licensee procedures
  - Industry Standards such as NQA-1

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### Potential Impact on Existing Guidance

- Licensees commit to QA program requirements such as NQA-1 in licensing documents (e.g. Safety Analysis Report, etc.)
- Licensees develop procedures and processes based upon industry guidance
- Any changes to QA program requirements or industry guidance will result in each licensee having to:
  - Perform a **thorough review of the new verbiage**
  - Confirm that the intent of any new **verbiage is understood**
  - Incorporate any new requirements, guidance, or terminology in **existing processes and procedures**

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### Potential Impact - Integrating New Requirements

- Word-by-word comparison to ensure understanding and verbatim compliance
- Review and possible revision of procedures
  - References, Terminology, Intentions
- Review and possible revision of forms and templates
- Review and possible changes to information systems (followed by testing and implementation)

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### Potential Impact - Integrating New Requirements

- Review and update of training materials
  - Licensee courses
  - EPRI courses
  - Courses offered by boutique vendors / consultants
- Devote resources to development of new industry guidance documents
  - Address any changes in commercial grade item dedication requirements or terminology
  - Address “Software dedication”
    - Development of “how to” guidance for dedication of commercial grade software

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### Opportunities for Clarification

- Clarify definition of “dedication” in 10CFR21
- Clarify definition of Commercial grade “item”
  - Part 50 vs. parts 34, 40, 60, 61, 70, 71, 72
- Endorsement of existing guidance for the application of sampling methods in commercial grade dedication
- Software dedication vs. commercial grade item dedication

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### Strength in Collaboration

- Working together, regulators and industry can:
  - Identify gaps and opportunities for clarification
  - Ensure changes increase assurance that an item will perform its safety function(s)
  - Develop clear language that minimizes the likelihood of misinterpretation
- More importantly
  - We can do the right thing
  - We can promote consistent and effective implementation of new guidance
  - We can promote expedient implementation of new guidance

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